U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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Commonly Asked Questions About BSE in Products Regulated by FDA's Center for Food Safety and Applied Nutrition (CFSAN)

In light of the December 23, 2003, diagnosis of BSE in a single cow that had been imported into the United States, CFSAN has reviewed the products it regulates to ensure their safety.

What is "Mad Cow Disease" (Bovine Spongiform Encephalopathy/BSE)?

Mad Cow Disease is the commonly used name for Bovine Spongiform Encephalopathy (BSE), a slowly progressive, degenerative, fatal disease affecting the central nervous system of adult cattle. Since 1990, the U.S. Department of Agriculture (USDA) has conducted aggressive surveillance of the highest risk cattle going to slaughter in the United States, in which 10,000- 20,000 animals per year have been tested. To date, the only cow that has been found to be affected with BSE was the one diagnosed with BSE in December 2003.

What causes BSE?

The exact cause of BSE is not known but it is generally accepted by the scientific community that infectious forms of a type of protein, prions, normally found in animals cause BSE. In cattle with BSE, these abnormal prions initially occur in the small intestines and tonsils, and are found in central nervous tissues, such as the brain and spinal cord, and other tissues of infected animals experiencing later stages of the disease.

Was a case of BSE identified in the U.S. in December 2003?

Yes, the USDA surveillance program identified the first BSE case in the U.S. in a dairy cow in Washington State. The cow was bought from a farm in Canada.

Did meat and meat products from the BSE cow enter the food supply?

As soon as the BSE case was identified, both USDA and FDA activated their BSE Emergency Response Plans and USDA immediately recalled the meat. Meat that did enter the food supply was quickly traced and was removed from the marketplace. Moreover, all the organs in which infectious prions occur were removed at slaughter and did not enter the food supply. Scientific research indicates that muscle meat is not a source of infectious prions. As a result of the agencies' quick actions and the removal of organs that contain infectious prions, there is no significant risk from products of this animal.

FDA and state inspectors located all other parts of the animal, and rendering plants that processed this material from the BSE cow voluntarily held the material. None of this material left the control of the companies and entered commercial distribution.

Will there be additional cases?

Regulatory measures to prevent introduction of BSE into U.S. cattle herds and contamination of U.S. foods and food products are being reviewed and updated. Since 1989, the USDA has banned imports of live ruminants, such as cattle, sheep and goats, and most products from these animals from countries known to have BSE. This ban was extended to all Europe in 1997. The FDA prohibited the use of ruminant protein in the manufacture of animal feed intended for cows and other ruminants in 1997 and extended the prohibition in 2001 to forbid use of all mammalian protein in ruminant feed. See the FDA/CVM website at www.fda.gov/cvm for further information on the "ruminant feed ban".

Under an Import Alert, FDA also prevents U.S. entry of cosmetic and dietary supplement ingredients containing high risk bovine materials from animals originating in BSE countries.

In 1998, the USDA commissioned the Harvard Center for Risk Analysis to conduct an analysis and evaluation of the U.S. regulatory measures to prevent the spread of BSE in the U.S. and to reduce the potential exposure of U.S. consumers to BSE. The Harvard study concluded that if introduced, due to the preventive measures currently in place in the U.S., BSE is extremely unlikely to become established in the United States. Should BSE enter the United States, the Harvard study concluded that only a small amount of potentially infective tissues would likely reach the human food supply.

Furthermore, on Jan. 8, 2004, the USDA's Food Safety and Inspection Service issued four new rules to enhance safeguards against BSE. Details on these rules may be found at the USDA website, www.usda.gov.

Does BSE affect people?

There is a disease similar to BSE called Creutzfeldt-Jacob Disease (CJD) that is found in people. A variant form of CJD (vCJD) is believed to be caused by eating contaminated beef products from BSE-affected cattle. To date, there have been 155 confirmed and probable cases of vCJD worldwide among the hundreds of thousands of people that may have consumed BSE-contaminated beef products. The one reported case of vCJD in the United States is in a young woman who contracted the disease while residing in the UK and developed symptoms after moving to the U.S.

What additional measures are being taken to ensure food safety in the U.S. from BSE?

Since 1989, the FDA and other federal agencies have had ongoing regulatory measures in place to prevent BSE contamination of U.S. food and food products since 1989. Following the identification in a Washington state dairy herd of the BSE-positive cow imported from Canada, the USDA has issued four new regulations containing additional safeguards to further minimize risk for introduction of the BSE agent into the U.S. food supply. These safeguards include:

a. A ban on use of live, but non-ambulatory cattle from entering the human food supply
b. A ban on use of organs, from cattle older than 30 months, in which infectious prions occur and the tonsils and small intestine of cattle of all ages for human food
c. Restrictions on techniques to mechanically remove meat from bones, and
d. Meat from tested animals will not be certified as USDA-inspected until test results are final.

See the USDA website www.usda.gov for further information.

FDA fully supports the safety policies announced by the USDA, which build on the principles and procedures that FDA and USDA have developed since 1989. These protective measures will add an additional layer of protection for the American public.

FDA will fulfill its increased responsibilities for protecting the safety of the food and animal feed supply.

Is the food in the U.S. likely to be a BSE risk to consumers?

FDA and other federal agencies have had preventive measures in place to reduce the U.S. consumer's risk of exposure to any BSE-contaminated meat and food products. Since 1989, the USDA had prohibited the importation of live animals and animal products from BSE-positive countries. Since 1997 the FDA has prohibited the use of most mammalian protein in the manufacture of ruminant feed. FDA continues to implement policies to keep safe all FDA-regulated products, including food, food ingredients, dietary supplements, drugs, vaccines, and cosmetics from risk of any BSE-contaminated bovine material.

Is cow's milk a source of BSE?

Scientific research indicates that BSE cannot be transmitted in cow's milk, even if the milk comes from a cow with BSE.

In the process of locating herd mates of the BSE-positive cow in Washington state, at least one dairy herd was quarantined. Is there any known risk to consumers that milk from this herd contains the BSE infectious agent or may transmit BSE?

No, because BSE is not transmitted through milk. It is FDA's opinion, based on the totality of scientific data available to the agency, that milk from healthy cows from the same herd in which the BSE-positive cow was found does not present a BSE risk to consumers. Likewise, milk from healthy cows in other herds quarantined because one of the cows is identified as a previous herd mate of the BSE-positive cow does not present a BSE risk to consumers. If the cows in a herd are healthy and not clinically affected by BSE, there is no scientific basis for restricting that milk.

Can milk be infected with BSE from a BSE-positive cow?

No detectable infectivity in cow's milk has been reported from any BSE-infected cows. Infectious prions have not been detected by bioassay of milk from cattle with BSE.

Are milk and milk products BSE-safe?

Yes. The World Health Organization (WHO) has stated that tests on milk from BSE-infected animals have not shown any BSE infectivity, and there is evidence from other animal and human transmissible spongiform encephalopathy studies to suggest that milk does not transmit these diseases. Milk and milk products, even in countries with a high incidence of BSE are, therefore, considered safe.

Should milk from a BSE-positive cow be discarded?

Even though milk does not transmit BSE, the milk from a cow with BSE should be discarded. The Food, Drug, and Cosmetic Act and state milk safety regulations require that products from animals with any disease not be used for human use. This is consistent with actions taken in the U.K, and with WHO recommendations on human use of products from BSE cows.

Does the use of bovine-derived ingredients in dietary supplements mean that they are not safe?

No. The risk to human health from BSE in the United States food supply, which includes dietary supplements, is extremely low. Since 1992, FDA has advised dietary supplement manufacturers and distributors that they should take steps to ensure that no dietary supplement ingredients come from cattle born, raised or slaughtered in any country known to have BSE or that has inadequate methods to detect and control it. We have also had import procedures in place since then to prevent the importation of bulk ingredients and finished dietary supplements that contain bovine-derived ingredients from so-called BSE-countries. Also, the vast majority of cattle-derived ingredients are obtained from U.S. sources or from countries not known to have BSE.

Since the BSE-positive cow was discovered in the U.S., does that mean that dietary supplements made with domestic ingredients might be unsafe?

No. Like all foods that are made using bovine-derived ingredients, the procedures that FDA and USDA have had in place to ensure the safety of the food supply should give consumers confidence that their food, including dietary supplements, is safe. Even though an imported BSE-positive cow was identified in the U.S., the risk to human health from dietary supplements and other foods containing bovine-derived ingredients remains extremely low.

What steps is FDA currently taking to ensure the safety of dietary supplements that contain bovine ingredients?

FDA continues to monitor dietary supplements and their ingredients when they enter the country. Those containing bovine-derived ingredients from cattle originating in prohibited countries are prohibited entry into the US. In addition, the restrictions on the use of certain cattle and cattle tissues in human food that were recently announced by USDA will also reduce the risks that potentially infective tissue is used in dietary supplements. FDA is exploring what further safeguards may be needed to provide greater assurance to consumers that dietary supplements and other foods remain safe. Most ingredients used to produce dietary supplements and most other food ingredients come from cattle that are slaughtered when they are less than 30-months of age and, because of their age, present little risk of being BSE-positive.

Given the recent BSE case in Washington State, should consumers be concerned about cosmetics made using tallow from the rendering process?

No. The World Health Organization considers tallow to be a low risk for transmission of BSE. Specifically, the rendering process separates fats from proteins. Because the disease is transmitted by prions, which are a type of protein, they would be separated by the rendering process from the tallow or fat, which is the portion that goes into cosmetics. Additionally, the tallow is processed with excessive heat and pressure which may further minimize any risk of infectivity prior to use in cosmetics. Nevertheless, the agency has encouraged cosmetic manufacturers to acquire tallow from sources that do not include cattle with BSE.

What about the use of gelatin, another bovine-related material, in cosmetics and dietary supplements and other foods?

Gelatin may be derived from cattle bones and hides, which are considered low risk tissues for BSE transmission, although most food-grade gelatin in the U.S. is of porcine origin. In 1997, FDA published guidance for gelatin manufacturing that recommends that bones and hides from cattle with any neurologic disease not be used to manufacture gelatin. The guidance also recommends that the heads, spines, and spinal cords of cattle from BSE countries not be used in gelatin production. The manufacturing process for gelatin further reduces any BSE risk for humans to negligible levels. The agency is currently revising the 1997 guidance.

When and how did BSE in cattle occur?

BSE in cattle was first reported in 1986 in the United Kingdom (UK). The exact origins of BSE remain uncertain but it is thought that cattle initially may have become infected when fed feed contaminated with scrapie-infected sheep meat-and-bone meal (MBM). Scrapie is a prion disease in sheep similar to BSE in cattle. The scientific evidence suggests that the U.K. BSE outbreak in cattle then was expanded by feeding BSE-contaminated cattle protein (MBM) to calves. The definitive nature of the BSE agent is not completely known. The agent is thought to be a modified form of a protein, called a prion, which becomes infectious and accumulates in neural tissues causing a fatal, degenerative, neurological disease. These abnormal prions are resistant to common food disinfection treatments, such as heat, to reduce or eliminate their infectivity or presence. Research is ongoing to better understand TSE diseases and the nature of prion transmission.

Is BSE in cattle the same disease as CWD in deer and elk in the U.S.?

BSE is a Transmissible Spongiform Encephalopathy (TSE), a family of similar diseases that may infect certain species of animals and people such as scrapie in sheep and goats, bovine spongiform encephalopathy (BSE) in cattle, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jacob disease (CJD) in people.

To date, there is no scientific evidence that BSE in cattle is related to CWD in deer and elk. Research is continuing but there is no evidence that either BSE or CWD can be transmitted between cattle, deer, or elk. FDA is working closely with other government agencies and the public health community to address CWD in wild and domesticated deer and elk herds. Wildlife and public health officials advise people not to harvest, handle, or consume any wild deer or elk that appear to be sick, regardless of the cause, especially in those states where CWD has been detected.

What countries have reported cases of BSE or are considered to have a substantial risk associated with BSE?

These countries are: Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Federal Republic of Yugoslavia, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Liechtenstein, Luxembourg, former Yugoslavia Republic of Macedonia, The Netherlands, Norway, Oman, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Japan, and United Kingdom (Great Britain including Northern Ireland and the Falkland Islands).

Canada (May 2003) and the U.S. (December 2003) each have recently reported one BSE-positive cow but remain countries considered to have a low risk. The U.S. BSE-positive cow reported in December 2003 was confirmed to have been imported from Canada in 2001.

This document was issued in January 2004.
For more recent information on Bovine Spongiform Encephalopathy (BSE)
See http://www.fda.gov/oc/opacom/hottopics/bse.html